IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE DEUTSCHLAND GMBH & CO. KG, Plaintiffs, v. HETERO USA INC., HETERO LABS LIMITED, and HETERO LABS LIMITED UNIT-III Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs AbbVie Inc. and AbbVie Deutschland GmbH & Co. KG (collectively "AbbVie"), by way of this Complaint against Hetero USA Inc., Hetero Labs Limited, and Hetero-Unit-III (collectively "Hetero" or "Defendants") state as follows:

THE PARTIES

1. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is a global biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Plaintiff AbbVie Deutschland GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Mainzer Straße 81, 65189 Wiesbaden, Germany, which is governed by its General Partner, AbbVie Komplentar GmbH, and is a wholly-owned foreign subsidiary of AbbVie Inc.

3. On information and belief, Defendant Hetero USA Inc. ("Hetero USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal

place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854, and is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South Dupont Highway, Dover, Delaware 19901) for the receipt of service of process.

4. On information and belief, Defendant Hetero Labs Limited ("Hetero Labs") is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Andhra Pradesh, India.

5. On information and belief, Hetero Labs is a parent corporation of Hetero USA.

6. On information and belief, Defendant Hetero Labs Limited Unit-III ("Hetero Unit-III") is an Indian corporation, which is a division of Hetero Labs, having a principal place of business at 22-110, Industrial Development Area, Jeedimetla, Hyderabad - 500-055, Andra Pradesh, India.

7. On information and belief, Hetero USA acts as a U.S. Food and Drug Administration ("FDA") Regulatory Agent for Hetero Unit-III.

8. On information and belief, the acts of Hetero USA complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Hetero Labs and Hetero Unit-III.

9. On information and belief, the acts of Hetero Labs complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Hetero USA and Hetero Unit-III.

10. On information and belief, the acts of Hetero Unit-III complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Hetero USA and Hetero Labs.

11. On information and belief, Hetero USA, Hetero Labs, and Hetero Unit-III act as an integrated business which engages in the formulation, manufacture, and sales of various generic drug products, and regularly conduct business throughout the United States, including in the State of Delaware, at least through participation in the sales of or selling of those products.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of: (1) United States Patent Number 6,037,157 B1 as amended by the Ex Parte Reexamination Certificate issued May 24, 2013, also known as Number 6,037,157 C1 (together "the '157 Patent"); (2) United States Patent Number 6,703,403 B2 ("the '403 Patent"); (3) United States Patent Number 7,148,359 B2 ("the '359 Patent"); (4) United States Patent Number 7,364,752 B1 as amended by the Inter Partes Reexamination Certificate issued January 23, 2015, also known as Number 7,364,752 C1 (together "the '752 Patent"); (5) United States Patent Number 8,025,899 ("the '899 Patent"); (6) United States Patent Number 8,268,349 B2 ("the '349 Patent"); (7) United States Patent Number 8,399,015 B2 ("the '015 Patent"); (8) United States Patent Number 8,309,613 ("the '613 Patent"); (9) United States Patent Number 8,377,952 ("the '952 Patent"); (10) United States Patent Number 8,470,347 B2 ("the '347 Patent"); and (11) United States Patent Number 8,691,878 B2 ("the '878 Patent"). This civil action arises under the United States Patent Laws, Title 35, United States Code, §§ 1 et seq., in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to Abbreviated New Drug Application ("ANDA") Number 205741 ("Hetero's ANDA 205741"), which Hetero filed or caused to be filed under 21 U.S.C. § 355(j) with the FDA for approval to market a generic copy of AbbVie's successful Kaletra® tablet product that is sold in the United States.

JURISDICTION AND VENUE

13. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

14. On information and belief, this Court has personal jurisdiction over each Defendant.

15. On information and belief, Hetero Labs, including by and through its division Hetero Unit-III, and through Hetero USA, formulates, develops, markets, and sells active pharmaceutical ingredients ("API"), solid oral dosage forms, pharmaceutical formulations, and pharmaceutical products containing such API or pharmaceutical formulations (collectively "Hetero's Products"). Hetero Labs and Hetero Labs Limited Unit-III, through their U.S. regulatory agent Hetero USA, routinely files ANDAs seeking FDA approval to market its products in the United States.

16. On information and belief, Hetero Labs, directly or through Hetero USA, Hetero Unit-III, or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes or causes to be distributed in Delaware and throughout the United States. On information and belief, Hetero Labs, either directly or through Hetero USA or through one or more of its subsidiaries, agents, or distributors, markets, sells, or distributes a substantial volume of its pharmaceutical products in Delaware.

17. On information and belief, Hetero Unit-III, including as a division of Hetero Labs and through Hetero USA, formulates, develops, markets, and sells Hetero's Products. Hetero

Labs and Hetero Labs Limited Unit-III, through their U.S. regulatory agent Hetero USA, routinely files ANDAs seeking FDA approval to market its products in the United States.

18. On information and belief, Hetero Unit-III, directly or through Hetero Labs, Hetero USA, or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes or causes to be distributed in Delaware and throughout the United States. On information and belief, Hetero Unit-III, either directly or through Hetero USA or through one or more of its subsidiaries, agents, or distributors, markets, sells, or distributes a substantial volume of its pharmaceutical products in Delaware.

19. On information and belief, Hetero USA, either directly or through one or more of its subsidiaries, affiliates, agents, distributors, or parent corporations (for example, including, but not limited to, Hetero Labs and Hetero Unit-III), seeks FDA approval for, markets, sells, or distributes a substantial volume of Hetero's Products in this judicial district, or actively participates in those activities. On information and belief, Hetero USA purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

20. On information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero USA, either directly or through one or more of its subsidiaries, agents, or distributors, markets, sells, or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Hetero USA complained of herein were done at the direction of, with the authorization of, or with the

cooperation, participation, and assistance of Hetero Labs. In a letter dated August 20, 2015 notifying AbbVie of the submission to the FDA of Hetero's ANDA 205741, Hetero USA described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit-III, a division of Hetero Labs Limited . . . ."

21. Hetero USA's acts, and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs, are also attributable to Hetero Labs and Hetero Unit-III for jurisdictional purposes.

22. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Hetero's ANDA 205741, which is the subject of this lawsuit. On information and belief, Hetero USA's and Hetero Unit-III's actions relating to Hetero's ANDA 205741 complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of, and at least in part for the benefit of, Hetero Labs.

23. On information and belief, Hetero USA is a Delaware corporation, is registered to do business in Delaware, and is the U.S. FDA Regulatory Agent for Hetero Unit-III.

24. On information and belief, Hetero Unit-III is a division of Hetero Labs.

25. On information and belief, Hetero USA, Hetero Unit-III, and Hetero Labs operate as an integrated business, ultimately controlled by Hetero Labs.

26. On information and belief, Defendants have collaborated to develop, seek FDA approval for, manufacture, import, distribute, and sell pharmaceutical products (generic drug products manufactured and sold pursuant to approved ANDAs) in the United States, and in Delaware, including this judicial district.

27. On information and belief, Defendants acted in concert to seek approval from the FDA to market generic copies of AbbVie's Kaletra® tablets that are the subject of Hetero's ANDA 205741 throughout the United States and in this judicial district.

28. Hetero USA and Hetero Labs have admitted that this Court has jurisdiction over them in *Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 12-305, D.I. 47 at ¶ 42. This Court has jurisdiction over Hetero USA and Hetero Labs by virtue of this admission.

29. Hetero USA, Hetero Labs, and Hetero Unit-III have availed themselves of this forum previously for the purpose of litigating patent disputes. For example, Hetero USA, Hetero Labs, and Hetero Unit-III have filed counterclaims for declaratory judgment. *See, e.g., AbbVie Inc. et al. v. Hetero USA Inc. et al.*, C.A. No. 14-543; *AbbVie Inc. v. Hetero USA Inc. et al.*, C.A. Nos. 13-852 & 14-1137; *Cephalon Inc. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 15-179; *Otsuka Pharmaceutical Co. Ltd. v. Hetero USA Inc. et al.*, C.A. No. 14-421; *Pfizer Inc. et al v. Hetero USA Inc. et al.*, C.A. No. 13-2021; *Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 12-305; *Kissei Pharm. Co. Ltd. et al. v. Hetero USA Inc. et al.*, C.A. No. 13-1091.

30. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, or sales of pharmaceutical products to residents of this judicial district, and the fact that they have availed themselves of the rights afforded in this judicial district.

31. This Court also has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, Defendants have committed, or aided, abetted, contributed to, or

participated in, the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to AbbVie Inc., a Delaware corporation.

32. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, Defendants have sent, or aided, abetted, contributed to, or participated in, the sending of a letter, dated August 20, 2015, purporting to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug & Cosmetic Act and Under 21 C.F.R. § 314.95" for Hetero's ANDA 205741 ("Hetero's Notice Letter") to AbbVie Inc., a Delaware corporation.

33. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400.

BACKGROUND

34. AbbVie Inc. is the holder of approved New Drug Application ("NDA") No. 21-906 for lopinavir/ritonavir tablets 200/50 mg and 100/25 mg, which AbbVie manufactures, markets, and sells under the trademark Kaletra®.

35. On information and belief, Hetero USA, Hetero Labs, and Hetero Unit-III acted in concert to file with the FDA Hetero's ANDA 205741 under 21 U.S.C. § 355(j), seeking FDA approval to market a 200/50 mg dosage strength of generic lopinavir/ritonavir tablets ("Hetero's Generic Lopinavir/Ritonavir Tablets") as generic copies of AbbVie's Kaletra® tablets in the United States.

36. Hetero's ANDA 205741 seeks FDA approval of a pharmaceutical composition comprising ritonavir and lopinavir in 200 mg/50 mg tablet dosage form and strength.

37. On or about August 21, 2015, AbbVie Inc. received Hetero's Notice Letter. Hetero's Notice Letter notified AbbVie that Hetero had filed Hetero's ANDA 205741, seeking approval to market Hetero's Generic Lopinavir/Ritonavir Tablets prior to the expiration of the '157, '403, '359, '752, '899, '349, '015, '613, '952, '347, and '878 Patents.

38. On information and belief, Hetero intends to capture some of the market for Kaletra® products with Hetero's Generic Lopinavir/Ritonavir Tablets, and induce healthcare providers (such as doctors) who currently prescribe Kaletra® products and patients who currently take Kaletra® products to switch to Hetero's Generic Lopinavir/Ritonavir Tablets.

THE PATENTS-IN-SUIT

39. The '157 Patent was originally duly and legally issued by the United States Patent and Trademark Office ("PTO") on March 14, 2000, as United States Patent Number 6,037,157 B1. The '157 Patent was the subject of two Ex Parte reexamination proceedings before the PTO. On May 24, 2013, after the conclusion of the first-filed reexamination proceeding, the PTO issued an Ex Parte Reexamination Certificate, which amended the '157 Patent as United States Patent Number 6,037,157 C1. AbbVie Inc. is the owner by assignment of the '157 Patent and has the right to sue for infringement thereof. AbbVie lists the '157 Patent in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 21-906. A true and correct copy of the '157 Patent, including its Reexamination Certificate, is attached as Exhibit A.

40. The '403 Patent was duly and legally issued by the PTO on March 9, 2004. AbbVie Inc. is the owner by assignment of the '403 Patent and has the right to sue for infringement thereof. AbbVie lists the '403 Patent in the Orange Book for NDA No. 21-906. The '403 patent is currently the subject of an Ex Parte reexamination proceeding at the PTO. A true and correct copy of the '403 Patent is attached as Exhibit B.

41. The '359 Patent was duly and legally issued by the PTO on December 12, 2006. AbbVie Inc. is the owner by assignment of the '359 Patent and has the right to sue for infringement thereof. The '359 Patent is current the subject of two Ex Parte reexamination

proceedings at the PTO. AbbVie lists the ’359 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the ’359 Patent is attached as Exhibit C.

42. The ’752 Patent was originally duly and legally issued by the PTO on April 29, 2008, as United States Patent Number 7,364,752 B1. The ’752 Patent was the subject of reexamination proceedings before the PTO. On January 23, 2015, after the conclusion of the reexamination proceedings, the PTO issued an Inter Partes Reexamination Certificate, which amended the ’752 Patent as United States Patent Number 7,364,752 C1. AbbVie Inc. is the owner by assignment of the ’752 Patent and has the right to sue for infringement thereof. AbbVie lists the ’752 Patent in the Orange Book for NDA 21-906. A true and correct copy of the ’752 Patent, including its Reexamination Certificate, is attached as Exhibit D.

43. The ’899 Patent was duly and legally issued by the PTO on September 27, 2011. AbbVie Inc. is the owner by assignment of the ’899 Patent and has the right to sue for infringement thereof. AbbVie lists the ’899 Patent in for NDA No. 21-906. A true and correct copy of the ’899 patent is attached as Exhibit E.

44. The ’349 Patent was duly and legally issued by the PTO on September 18, 2012. AbbVie Inc. is the owner by assignment of the ’349 Patent and has the right to sue for infringement thereof. AbbVie lists the ’349 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the ’349 Patent is attached as Exhibit F.

45. The ’613 Patent was duly and legally issued by the PTO on November 13, 2012. AbbVie Inc. is the owner by assignment of the ’613 Patent and has the right to sue for infringement thereof. AbbVie lists the ’613 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the ’613 Patent is attached as Exhibit G.

46. The ’952 Patent was duly and legally issued by the PTO on February 19, 2013. AbbVie Inc. is the owner by assignment of the ’952 Patent and has the right to sue for infringement thereof. AbbVie lists the ’952 Patent in the Orange Book for NDA 21-906. A true and correct copy of the ’952 Patent is attached as Exhibit H.

47. The ’015 Patent was duly and legally issued by the PTO on March 19, 2013. AbbVie Inc. is the owner by assignment of the ’015 Patent and has the right to sue for infringement thereof. AbbVie lists the ’015 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the ’015 Patent is attached as Exhibit I.

48. The ’347 Patent was duly and legally issued by the PTO on June 25, 2013. AbbVie Deutschland GmbH & Co. KG is the owner by assignment of the ’347 Patent and has the right to sue for infringement thereof. AbbVie lists the ’347 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the ’347 Patent is attached as Exhibit J.

49. The ’878 Patent was duly and legally issued by the PTO on April 8, 2014. AbbVie Inc. is the owner by assignment of the ’878 Patent and has the right to sue for infringement thereof. AbbVie lists the ’878 Patent in the Orange Book for NDA 21-906. A true and correct copy of the ’878 Patent is attached as Exhibit K.

FIRST COUNT
PATENT INFRINGEMENT OF THE ’157 PATENT

50. Paragraphs 1-49 are incorporated herein by reference.

51. On information and belief, Defendants acted in concert to file and have maintained Hetero’s ANDA 205741 in order to obtain approval to market Hetero’s Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the ’157 Patent.

52. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '157 Patent are purportedly invalid, unenforceable, and/or not infringed.

53. On information and belief, Hetero has represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

54. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '157 Patent constitutes infringement of one or more claims of the '157 Patent, either literally or under the doctrine of equivalents.

55. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '157 Patent constitutes infringement of one or more claims of the '157 Patent, either literally or under the doctrine of equivalents.

56. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, one of the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

57. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once Hetero's ANDA 205741 is approved by the FDA, would actively induce infringement of at least one of the claims of the '157 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

58. Defendants have knowledge and are aware of AbbVie's '157 Patent, as evidenced by Hetero's Notice Letter.

59. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '157 Patent, either literally or under the doctrine of equivalents.

60. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '157 Patent, either literally or under the doctrine of equivalents.

61. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '157 Patent, either literally or under the doctrine of equivalents.

62. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '157 Patent, either literally or under the doctrine of equivalents.

63. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will

directly infringe at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

64. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

65. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’157 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

66. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

67. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered used by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’157 Patent by patients or medical practitioners. On information and belief administration of Hetero’s Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know will

occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '157 Patent.

68. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '157 Patent, either literally or under the doctrine of equivalents.

69. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '157 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT
PATENT INFRINGEMENT OF THE '403 PATENT

70. Paragraphs 1-69 are incorporated herein by reference.

71. On information and belief, Defendants acted in concert to file and have maintained Hetero's ANDA 205741 in order to obtain approval to market Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '403 Patent.

72. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '403 Patent are purportedly invalid, unenforceable, and/or not infringed.

73. On information and belief, Hetero has represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

74. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '403 Patent constitutes infringement of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

75. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '403 Patent constitutes infringement of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

76. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, one of the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

77. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once Hetero's ANDA 205741 is approved by the FDA, would actively induce infringement of at least one of the claims of the '403 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

78. Defendants have knowledge and are aware of AbbVie's '403 Patent, as evidenced by Hetero's Notice Letter.

79. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

80. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

81. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

82. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

83. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

84. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

85. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '403 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Hetero's Generic Lopinavir/Ritonavir Tablets.

86. On information and belief, therefore, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

87. On information and belief, Hetero's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '403 Patent by patients or medical practitioners. On information and belief administration of Hetero's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by

patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '403 Patent.

88. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

89. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '403 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT
PATENT INFRINGEMENT OF THE '359 PATENT

90. Paragraphs 1–89 are incorporated herein by reference.

91. On information and belief, Defendants acted in concert to file and have maintained Hetero's ANDA 205741 in order to obtain approval to manufacture, use, and market Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '359 Patent.

92. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 Patent are purportedly invalid, unenforceable, and/or not infringed.

93. On information and belief, Defendants have represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

94. Under 35 U.S.C. §§ 271(a) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '359 Patent constitutes infringement of one or more claims of the '359 Patent, either literally or under the doctrine of equivalents.

95. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import their Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '359 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

FOURTH COUNT
PATENT INFRINGEMENT OF THE '752 PATENT

96. Paragraphs 1–95 are incorporated herein by reference.

97. On information and belief, Defendants acted in concert to file and have maintained Hetero's ANDA 205741 in order to obtain approval to manufacture, use, and market Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '752 Patent.

98. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a

certification that the claims of the ’752 Patent are purportedly invalid, unenforceable, and/or not infringed.

99. On information and belief, Defendants have represented to the FDA in Hetero’s ANDA 205741 that Hetero’s Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie’s Kaletra® tablets.

100. Under 35 U.S.C. §§ 271(a) and (e)(2)(A), the submission to the FDA of Hetero’s ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero’s Generic Lopinavir/Ritonavir Tablets before the expiration date of the ’752 Patent constitutes infringement of one or more claims of the ’752 patent, either literally or under the doctrine of equivalents.

101. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of Hetero’s ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero’s Generic Lopinavir/Ritonavir Tablets before the expiration date of the ’752 Patent constitutes infringement of one or more claims of the ’752 Patent, either literally or under the doctrine of equivalents.

102. On information and belief, Defendants are actively seeking FDA approval to sell Hetero’s Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

103. On information and belief, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once Hetero’s ANDA 205741 is approved by the FDA, would actively induce infringement of at least one of the claims of the ’752 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

104. Defendants have knowledge and are aware of AbbVie's '752 Patent, as evidenced by Hetero's Notice Letter.

105. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

106. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

107. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

108. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

109. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will

directly infringe at least one claim of the ’752 Patent, either literally or under the doctrine of equivalents.

110. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’752 Patent, either literally or under the doctrine of equivalents.

111. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’752 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

112. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’752 Patent, either literally or under the doctrine of equivalents.

113. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’752 Patent by patients or medical practitioners. On information and belief administration of Hetero’s Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know will occur. On

information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '752 Patent.

114. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

115. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '752 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

FIFTH COUNT
PATENT INFRINGEMENT OF THE '899 PATENT

116. Paragraphs 1-115 are incorporated herein by reference.

117. On information and belief, Defendants acted in concert to file and have maintained Hetero's ANDA 205741 in order to obtain approval to manufacture, use, and market Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '899 Patent.

118. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '899 Patent are purportedly invalid, unenforceable, and/or not infringed.

119. On information and belief, Defendants have represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

120. Under 35 U.S.C. §§ 271(a) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '899 Patent constitutes infringement of one or more claims of the '899 Patent, either literally or under the doctrine of equivalents.

121. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '899 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SIXTH COUNT
PATENT INFRINGEMENT OF THE '349 PATENT

122. Paragraphs 1-121 are incorporated herein by reference.

123. On information and belief, Defendants acted in concert to file and have maintained Hetero's ANDA 205741 in order to obtain approval to manufacture, use, and market Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '349 Patent.

124. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a

certification that the claims of the ’349 Patent are purportedly invalid, unenforceable, and/or not infringed.

125. On information and belief, Defendants have represented to the FDA in Hetero’s ANDA 205741 that Hetero’s Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie’s Kaletra® tablets.

126. Under 35 U.S.C. §§ 271(a) and (e)(2)(A), the submission to the FDA of Hetero’s ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero’s Generic Lopinavir/Ritonavir Tablets before the expiration date of the ’349 Patent constitutes infringement of one or more claims of the ’349 Patent, either literally or under the doctrine of equivalents.

127. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero’s Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero’s ANDA 205741 for Hetero’s Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the ’349 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SEVENTH COUNT
PATENT INFRINGEMENT OF THE ’015 PATENT

128. Paragraphs 1–127 are incorporated herein by reference.

129. On information and belief, Defendants acted in concert to file and have maintained Hetero’s ANDA 205741 in order to obtain approval to manufacture, use, and market Hetero’s Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the ’015 Patent.

130. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’015 Patent are purportedly invalid, unenforceable, and/or not infringed.

131. On information and belief, Defendants have represented to the FDA in Hetero’s ANDA 205741 that Hetero’s Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie’s Kaletra® tablets.

132. Under 35 U.S.C. §§ 271(a) and (e)(2)(A), the submission to the FDA of Hetero’s ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero’s Generic Lopinavir/Ritonavir Tablets before the expiration date of the ’015 Patent constitutes infringement of one or more claims of the ’015 Patent, either literally or under the doctrine of equivalents.

133. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero’s Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero’s ANDA 205741 for Hetero’s Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the ’015 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

EIGHTH COUNT
PATENT INFRINGEMENT OF THE ’613 PATENT

134. Paragraphs 1-133 are incorporated herein by reference.

135. On information and belief, Defendants acted in concert to file and have maintained Hetero’s ANDA 205741 in order to obtain approval to manufacture, use, and market

Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '613 Patent.

136. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '613 Patent are purportedly invalid, unenforceable, and/or not infringed.

137. On information and belief, Defendants have represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

138. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '613 Patent constitutes infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

139. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '613 Patent constitutes infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

140. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

141. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once Hetero's ANDA 205741 is approved by the FDA, would actively induce infringement of at least one of the claims of the '613 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

142. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Hetero's Notice Letter.

143. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

144. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

145. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

146. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and,

therefore, will directly infringe at least one claim of the ’613 Patent, either literally or under the doctrine of equivalents.

147. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’613 Patent, either literally or under the doctrine of equivalents.

148. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’613 Patent, either literally or under the doctrine of equivalents.

149. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’613 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

150. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’613 Patent, either literally or under the doctrine of equivalents.

151. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be

administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’613 Patent by patients or medical practitioners. On information and belief administration of Hetero’s Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie’s rights under the ’613 Patent.

152. Defendants’ threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero’s Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the ’613 Patent, either literally or under the doctrine of equivalents.

153. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero’s Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero’s ANDA 205741 for Hetero’s Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the ’613 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

NINTH COUNT
PATENT INFRINGEMENT OF THE ’952 PATENT

154. Paragraphs 1-153 are incorporated herein by reference.

155. On information and belief, Defendants acted in concert to file and have maintained Hetero’s ANDA 205741 in order to obtain approval to manufacture, use, and market

Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '952 Patent.

156. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '952 Patent are purportedly invalid, unenforceable, and/or not infringed.

157. On information and belief, Defendants have represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

158. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '952 Patent constitutes infringement of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

159. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '952 Patent constitutes infringement of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

160. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

161. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once Hetero's ANDA 205741 is approved by the FDA, would actively induce infringement of at least one of the claims of the '952 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

162. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Hetero's Notice Letter.

163. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

164. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

165. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

166. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and,

therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

167. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

168. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

169. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’952 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

170. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

171. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be

administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’952 Patent by patients or medical practitioners. On information and belief administration of Hetero’s Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie’s rights under the ’952 Patent.

172. Defendants’ threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero’s Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

173. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero’s Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero’s ANDA 205741 for Hetero’s Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the ’952 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

TENTH COUNT
PATENT INFRINGEMENT OF THE ’347 PATENT

174. Paragraphs 1-173 are incorporated herein by reference.

175. On information and belief, Defendants acted in concert to file and have maintained Hetero’s ANDA 205741 in order to obtain approval to manufacture, use, and market

Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '347 Patent.

176. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '347 Patent are purportedly invalid, unenforceable, and/or not infringed.

177. On information and belief, Defendants have represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

178. Under 35 U.S.C. §§ 271(a) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '347 Patent constitutes infringement of one or more claims of the '347 Patent, either literally or under the doctrine of equivalents.

179. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '347 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

ELEVENTH COUNT
PATENT INFRINGEMENT OF THE '878 PATENT

180. Paragraphs 1–179 are incorporated herein by reference.

181. On information and belief, Defendants acted in concert to file and have maintained Hetero's ANDA 205741 in order to obtain approval to manufacture, use, and market Hetero's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '878 Patent.

182. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '878 Patent are purportedly invalid, unenforceable, and/or not infringed.

183. On information and belief, Defendants have represented to the FDA in Hetero's ANDA 205741 that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

184. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '878 Patent constitutes infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

185. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of Hetero's ANDA 205741 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '878 Patent constitutes infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

186. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

187. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once Hetero's ANDA 205741 is approved by the FDA, would actively induce infringement of at least one of the claims of the '878 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

188. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Hetero's Notice Letter.

189. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

190. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

191. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

192. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

193. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

194. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

195. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '878 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Hetero's Generic Lopinavir/Ritonavir Tablets.

196. On information and belief, therefore, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

197. On information and belief, Hetero's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '878 Patent by patients or medical practitioners. On information and belief administration of Hetero's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '878 Patent.

198. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

199. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, or import Hetero's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and 283, AbbVie is entitled to an order that the effective date of any approval of Hetero's ANDA 205741 for Hetero's Generic Lopinavir/Ritonavir Tablets be a date which is not earlier than the date of expiration of the '878 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

TWELFTH COUNT
DECLARATORY JUDGMENT AS TO THE '157 PATENT

200. Paragraphs 1-199 are incorporated herein by reference.

201. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

202. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '157 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '157 Patent and any additional periods of exclusivity.

203. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

204. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

205. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '157 Patent, either literally or under the doctrine of equivalents.

206. Defendants have knowledge and are aware of AbbVie's '157 Patent, as evidenced by Hetero's Notice Letter.

207. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to

actively induce infringement by others of one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

208. On information and belief, by the filing of Hetero’s ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero’s Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

209. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

210. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

211. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

212. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and,

therefore, will directly infringe at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

213. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’157 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

214. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

215. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’157 Patent by patients or medical practitioners. On information and belief, administration of Hetero’s Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie’s rights under the ’157 Patent.

216. If the FDA approves Hetero’s ANDA 205741, Defendants will make, sell, offer to sell, or import into the United States Hetero’s Generic Lopinavir/Ritonavir Tablets before the

expiration of the ’157 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

217. Defendants’ threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero’s Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

218. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the ’157 Patent.

219. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants’ threatened infringement of the ’157 Patent.

220. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

221. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

THIRTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE ’403 PATENT

222. Paragraphs 1-221 are incorporated herein by reference.

223. On information and belief, Defendants are actively seeking FDA approval to sell Hetero’s Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

224. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '403 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '403 Patent and any additional periods of exclusivity.

225. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

226. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

227. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '403 Patent, either literally or under the doctrine of equivalents.

228. Defendants have knowledge and are aware of AbbVie's '403 Patent, as evidenced by Hetero's Notice Letter.

229. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

230. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

231. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

232. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

233. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

234. On information and belief, Defendants are aware andhave knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '403 Patent, either literally or under the doctrine of equivalents.

235. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '403 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Hetero's Generic Lopinavir/Ritonavir Tablets.

236. On information and belief, therefore, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '403 Patent, either literally or under the doctrine of equivalents.

237. On information and belief, Hetero's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '403 Patent by patients or medical practitioners. On information and belief administration of Hetero's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '403 Patent.

238. If the FDA approves Hetero's ANDA 205741, Defendants will make, sell, offer to sell, or import into the United States Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration of the '403 Patent, and will actively induce infringement by others under 35 U.S.C.

§ 271(b) of one or more claims of the ’403 Patent, either literally or under the doctrine of equivalents.

239. Defendants’ threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero’s Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the ’403 Patent, either literally or under the doctrine of equivalents.

240. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the ’403 Patent.

241. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants’ threatened infringement of the ’403 Patent.

242. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

243. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FOURTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE ’359 PATENT

244. Paragraphs 1–243 are incorporated herein by reference.

245. On information and belief, Defendants are actively seeking FDA approval to sell Hetero’s Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

246. On information and belief, upon FDA approval of Hetero’s ANDA 205741, Defendants will infringe one or more claims of the ’359 Patent under 35 U.S.C. § 271(a), either

literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing Hetero's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '359 Patent and any additional periods of exclusivity.

247. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

248. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

249. On information and belief, therefore, Defendants' manufacture, importation, sale, or offer for sale of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

250. Defendants have knowledge and are aware of AbbVie's '359 Patent, as evidenced by Hetero's Notice Letter.

251. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '359 Patent.

252. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '359 Patent.

253. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

254. In view of the foregoing, there exists a substantial controversy between AbbVie and Hetero, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FIFTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '752 PATENT

255. Paragraphs 1–254 are incorporated herein by reference.

256. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

257. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing Hetero's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity.

258. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity.

259. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

260. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

261. On information and belief, therefore, Defendants' manufacture, importation, sale, or offer for sale of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

262. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents.

263. Defendants have knowledge and are aware of AbbVie's '752 Patent, as evidenced by Hetero's Notice Letter.

264. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

265. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

266. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

267. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

268. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

269. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

270. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Hetero's Generic Lopinavir/Ritonavir Tablets.

271. On information and belief, therefore, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

272. On information and belief, Hetero's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '752 Patent by patients or medical practitioners. On information and belief administration of Hetero's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '752 Patent.

273. If the FDA approves Hetero's ANDA 205741, Defendants will make, sell, offer to sell, or import into the United States Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration of the '752 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

274. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

275. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '752 Patent.

276. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '752 Patent.

277. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

278. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

SIXTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '899 PATENT

279. Paragraphs 1–278 are incorporated herein by reference.

280. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

281. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '899 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing Hetero's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '899 Patent and any additional periods of exclusivity.

282. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

283. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

284. On information and belief, therefore, Defendants' manufacture, importation, sale, or offer for sale of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '899 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

285. Defendants have knowledge and are aware of AbbVie's '899 Patent, as evidenced by Hetero's Notice Letter.

286. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '899 Patent.

287. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '899 Patent.

288. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

289. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

SEVENTIETH COUNT
DECLARATORY JUDGMENT AS TO THE '349 PATENT

290. Paragraphs 1–289 are incorporated herein by reference.

291. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

292. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '349 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing Hetero's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '349 Patent and any additional periods of exclusivity.

293. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

294. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

295. On information and belief, therefore, Defendants' manufacture, importation, sale, or offer for sale of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '349 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

296. Defendants have knowledge and are aware of AbbVie's '349 Patent, as evidenced by Hetero's Notice Letter.

297. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the ’349 Patent.

298. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants’ threatened infringement of the ’349 Patent.

299. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

300. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

EIGHTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE ’015 PATENT

301. Paragraphs 1–300 are incorporated herein by reference.

302. On information and belief, Defendants are actively seeking FDA approval to sell Hetero’s Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

303. On information and belief, upon FDA approval of Hetero’s ANDA 205741, Defendants will infringe one or more claims of the ’015 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing Hetero’s Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of Hetero’s ANDA 205741 shall be no earlier than the expiration date of the ’015 Patent and any additional periods of exclusivity.

304. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

305. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

306. On information and belief, therefore, Defendants' manufacture, importation, sale, or offer for sale of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '015 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

307. Defendants have knowledge and are aware of AbbVie's '015 Patent, as evidenced by Hetero's Notice Letter.

308. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '015 Patent.

309. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '015 Patent.

310. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

311. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

NINETEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '613 PATENT

312. Paragraphs 1–311 are incorporated herein by reference.

313. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

314. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '613 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '613 Patent and any additional periods of exclusivity.

315. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

316. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

317. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents.

318. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Hetero's Notice Letter.

319. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

320. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

321. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

322. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

323. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

324. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

325. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Hetero's Generic Lopinavir/Ritonavir Tablets.

326. On information and belief, therefore, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

327. On information and belief, Hetero's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '613 Patent by patients or medical practitioners. On information and belief administration of Hetero's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by medical practitioners

and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '613 Patent.

328. If the FDA approves Hetero's ANDA 205741, Defendants will make, sell, offer to sell, or import into the United States Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration of the '613 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

329. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

330. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '613 Patent.

331. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '613 Patent.

332. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

333. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

TWENTIETH COUNT
DECLARATORY JUDGMENT AS TO THE '952 PATENT

334. Paragraphs 1–333 are incorporated herein by reference.

335. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

336. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '952 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '952 Patent and any additional periods of exclusivity.

337. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

338. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

339. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '952 Patent, either literally or under the doctrine of equivalents.

340. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Hetero's Notice Letter.

341. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to

actively induce infringement by others of one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

342. On information and belief, by the filing of Hetero’s ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero’s Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

343. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

344. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

345. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

346. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and,

therefore, will directly infringe at least one claim of the ’952 Patent, either literally or under the doctrine of equivalents.

347. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’952 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

348. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

349. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’952 Patent by patients or medical practitioners. On information and belief administration of Hetero’s Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie’s rights under the ’952 Patent.

350. If the FDA approves Hetero’s ANDA 205741, Defendants will make, sell, offer to sell, or import into the United States Hetero’s Generic Lopinavir/Ritonavir Tablets before the

expiration of the ’952 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

351. Defendants’ threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero’s Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the ’952 Patent, either literally or under the doctrine of equivalents.

352. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the ’952 Patent.

353. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants’ threatened infringement of the ’952 Patent.

354. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

355. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

TWENTY-FIRST COUNT
DECLARATORY JUDGMENT AS TO THE ’347 PATENT

356. Paragraphs 1–355 are incorporated herein by reference.

357. On information and belief, Defendants are actively seeking FDA approval to sell Hetero’s Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

358. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '347 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, or importing Hetero's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '347 Patent and any additional periods of exclusivity.

359. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

360. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

361. On information and belief, therefore, Defendants' manufacture, importation, sale, or offer for sale of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '347 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

362. Defendants have knowledge and are aware of AbbVie's '347 Patent, as evidenced by Hetero's Notice Letter.

363. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '347 Patent.

364. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '347 Patent.

365. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

366. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

TWENTY-SECOND COUNT
DECLARATORY JUDGMENT AS TO THE '878 PATENT

367. Paragraphs 1–366 are incorporated herein by reference.

368. On information and belief, Defendants are actively seeking FDA approval to sell Hetero's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

369. On information and belief, upon FDA approval of Hetero's ANDA 205741, Defendants will infringe one or more claims of the '878 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA 205741 shall be no earlier than the expiration date of the '878 Patent and any additional periods of exclusivity.

370. On information and belief, Defendants intend to commence sales of Hetero's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

371. On information and belief, in Hetero's ANDA 205741, Defendants have represented to the FDA that Hetero's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

372. On information and belief, Defendants' offering to sell, sale, making, or importation of Hetero's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '878 Patent, either literally or under the doctrine of equivalents.

373. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Hetero's Notice Letter.

374. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage patients to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

375. On information and belief, by the filing of Hetero's ANDA 205741 with a proposed package insert having directions that encourage medical practitioners to administer Hetero's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

376. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero's Generic Lopinavir/Ritonavir Tablets and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

377. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero's Generic Lopinavir/Ritonavir Tablets and,

therefore, will directly infringe at least one claim of the ’878 Patent, either literally or under the doctrine of equivalents.

378. On information and belief, Defendants are aware and have knowledge that patients will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’878 Patent, either literally or under the doctrine of equivalents.

379. On information and belief, Defendants are aware and have knowledge that medical practitioners will administer Hetero’s Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the ’878 Patent, either literally or under the doctrine of equivalents.

380. On information and belief, Defendants know that they will aid and abet another’s direct infringement of at least one of the claims of the ’878 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Hetero’s Generic Lopinavir/Ritonavir Tablets.

381. On information and belief, therefore, Defendants’ offering to sell, sale, making, or importation of Hetero’s Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’878 Patent, either literally or under the doctrine of equivalents.

382. On information and belief, Hetero’s Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered by

patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '878 Patent by patient or medical practitioners. On information and belief administration of Hetero's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '878 Patent.

383. If the FDA approves Hetero's ANDA 205741, Defendants will make, sell, offer to sell, or import into the United States Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration of the '878 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

384. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Hetero's Generic Lopinavir/Ritonavir Tablets would infringe one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

385. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '878 Patent.

386. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '878 Patent.

387. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

388. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

a. declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of Hetero's ANDA 205741 to the FDA to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero's Generic Lopinavir/Ritonavir Tablets before the expiration of the '157, the '403, the '359, the '752, the '899, the '349, the '015, the '613, the '952, the '347, and the '878 patents was an act of infringement of each of the '157, the '403, the '359, the '752, the '899, the '349, the '015, the '613, the '952, the '347, and the '878 patents;

b. declaring that, under 35 U.S.C. § 271(a), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero's Generic Lopinavir/Ritonavir Tablets would constitute direct infringement of one or more claims of each of the '359, the '752, the '899, the '349, the '015, and the '347 patents;

c. declaring that, under 35 U.S.C. § 271(b) Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero's Generic Lopinavir/Ritonavir Tablets would constitute induced infringement of one or more claims of each of the '157, the '403, the '752, the '613, the '952, and the '878 patents;

d. enjoining Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining approval of Hetero's ANDA 205741 until the expiration of the '157, the '403, the '359, the '752, the '899, the '349, the '015, the '613, the '952, the '347, and the '878 patents and any additional periods of exclusivity;

e. enjoining Defendants and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Hetero's Generic Lopinavir/Ritonavir Tablets within the United States, or importing into the United States Hetero's Generic Lopinavir/Ritonavir Tablets, until the expiration of the '157, the '403, the '359, the '752, the '899, the '349, the '015, the '613, the '952, the '347, and the '878 patents and any additional periods of exclusivity;

f. ordering that the effective date of any FDA approval of Hetero's Generic Lopinavir/Ritonavir Tablets shall be no earlier than the expiration date of the '157, the '403, the '359, the '752, the '899, the '349, the '015, the '613, the '952, the '347, and the '878 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

g. declaring the '157, the '403, the '359, the '752, the '899, the '349, the '015, the '613, the '952, the '347, and the '878 patents valid and enforceable;

h. finding this to be an exceptional case and awarding AbbVie its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4)(C);

i. awarding AbbVie its costs and expenses in this action; and

j. awarding AbbVie any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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